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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/785,497	02/24/2004	Mark W. Becker	249.P2	9922

25000 7590 10/24/2007
GILEAD SCIENCES INC
333 LAKESIDE DR
FOSTER CITY, CA 94404

EXAMINER

MARTIN, PAUL C

ART UNIT	PAPER NUMBER
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1657

MAIL DATE	DELIVERY MODE
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10/24/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/785,497	Applicant(s) BECKER ET AL.	
	Examiner Paul C. Martin	Art Unit 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-13 and 15-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-13 and 15-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/20/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1, 3-13 and 15-17 are pending in this application and were examined on their merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 08/20/07 has been entered.

The rejection of Claims 1 and 3-7 under 35 U.S.C. § 102(b) as being anticipated by Shaw *et al.* (1997) has been withdrawn because the Applicant's arguments with regard to plasma being a tissue were found to be persuasive.

Claim Rejections - 35 USC § 103

Claims 1, 3-7 and 10-13 remain rejected under 35 U.S.C. § 103(a) as being unpatentable over Shaw *et al.* (1997) for reasons of record set forth in the Prior Action.

Claims 1, 3-7, 9-13, 15 and 16 remain rejected under 35 U.S.C. § 103(a) as being unpatentable over Shaw *et al.* (1997) in view of Glazier *et al.* (US 5,627,165) for reasons of record set forth in the Prior Action.

Claims 1, 3-8, 10-13 and 17 remain rejected under 35 U.S.C. § 103(a) as being unpatentable over Shaw *et al.* (1997) in view of Starret *et al.* (US 5,663,159) for reasons of record set forth in the Prior Action.

Response to Arguments

Applicant's arguments, see Remarks, filed 08/20/07, with respect to the rejection(s) of claim(s) 1, 3-7 under 35 U.S.C. 102 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn.

Applicant's arguments filed 08/20/07 have been fully considered but they are not persuasive.

The Applicant argues that Shaw *et al.* teaches the differential distribution of an active metabolite in plasma, not defined as a tissue as it contains no cells. Further, even if it were obvious to measure the level of metabolite compound in blood as opposed to plasma, Shaw *et al.* would not be measuring the level in different tissues only in tissue blood (Remarks, Pg. 1-2).

This is not found to be persuasive for the following reasons, Shaw *et al.* teaches the administration of the prodrug PMPA to plasma and to tissue homogenates of liver and intestine. In plasma, intestine and liver, the PMPA and prodrug compounds are shown to be enzymatically (esterase) degraded over time. As plasma is blood plasma with the cells removed (monocytes, macrophages, etc) but with the enzyme components remaining, one of ordinary skill in the art would have concluded that the degradation observed in plasma would have been the same in whole blood. Therefore, plasma and whole blood would have been recognized as functionally equivalent as they would provide equivalent results. One of ordinary skill in the art would certainly have recognized that whole blood and intestinal and liver homogenates were *different* tissues as defined in the instant specification.

Art Unit: 1657

The Applicant argues that as Shaw *et al.* and Glazier *et al.* allegedly address completely different distinct problems and objectives that there is not basis to combine them (Remarks, Pg. 2).

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). The teachings of both Shaw *et al.* and Glazier *et al.* and the response to the arguments that there is no basis for combining the two were discussed at length in the prior action.

Conclusion

No Claims are allowed.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114.

Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul C. Martin whose telephone number is 571-272-3348. The examiner can normally be reached on M-F 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1657

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Paul Martin
Examiner
Art Unit 1657

09/27/07

A handwritten signature in black ink, appearing to read "Jon Weber", with a large, stylized initial "J" and "W".

Jon Weber
Supervisory Patent Examiner